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09/446,681	03/14/2000	JOHN ANTHONY CHARLES ARCHER		2724

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EXAMINER

SANDALS, WILLIAM O

ART UNIT

PAPER NUMBER

1636

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21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/446,681

Applicant(s)

Archer et al.

Examiner
William Sandals

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1636



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 27, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 30-35, 37, and 49-61 is/are pending in the application.

4a) Of the above, claim(s) 31 and 49 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 30, 32-35, 37, and 50-61 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on Jan 27, 2003 is/are accepted or objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: approved disapproved by the Examiner.

 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

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DETAILED ACTION

Status of the Claims

1. Claims 30-35, 37 and 49-61 are pending. Claims 31 and 49 continue to be withdrawn as being drawn to non-elected inventions.
2. The rejection of claim 34 under 35 USC 112, first paragraph for lack of deposit has been overcome by amendment in Paper No. 17, filed September 12, 2002.
3. The rejection of claims 30, 32-35, 37 and 50-60 under 35 USC 112, first paragraph for lack of enablement has been overcome by the Declaration under 35 USC 1.132 of John Anthony Charles Archer, Paper No. 15, filed September 12, 2002.
4. The rejection of claims 50 and 57 under 35 USC 112, second paragraph, has been overcome by amendment in Paper No. 17.
5. The objection to claim 52 in the previous office action is sustained and repeated below.

Response to Amendment

6. The Declaration under 35 USC 1.132 of John Anthony Charles Archer, Paper No. 15, filed September 12, 2002 under 37 CFR 1.132 is sufficient to overcome the rejection of claims 30, 32-35, 37 and 50-60 based upon the evidence of expression of the claimed sequence encoding an *ohp* operon regulatory protein.

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Drawings

7. The drawings as submitted on January 27, 2003, have been approved by the draftsman.

Claim Objections

8. Claims 30, 33, 34, 52 and 54 are objected to because of the following informalities:

Claim 30, 33 and 34 recite “signal genes”. The art recognized term which is customarily used to describe these genes is “reporter genes”. Amendments to claims 30, 33, 34 to substitute the word “reporter” would provide consistency to the claim structure of claims 30, 33 and 34.

Claim 54 recites “the *R. corallina ohp* operon **described** in Fig. 4” (emphasis added). Previous claims 51-53 use the word “shown” in the same meaning as the word “described” in claim 54. Amendments to claim 54 to substitute the word “reporter” would provide consistency to the claim structure of claim 54. Support for this amendment can be found in the instant specification at the top of page 5.

Claim 52 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 52 is drawn to a nucleic acid molecule from codon 295 to codon 1035 of the sequence shown in figure 4. Claim 52 depends from claim 51 which claims a nucleic acid molecule from codon 295 to codon 1035 of the sequence shown in figure 4 (where the region from base 295 to base 1035 encodes an amino acid sequence). Claim 52 is therefore

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drawn to the identical subject matter of claim 51. In the alternative, amending claim 51 to depend from claim 52 would cure this defect since the additional limitation of the amino acid sequence further defines the claimed nucleic acid.

9. Appropriate correction is required.

Response to Arguments

10. With respect to the requirement for new formal drawings in the previous office action, Applicant has asserted that the objection to the drawings is improper, and has cited Article 27 (1) of the Patent Cooperation Treaty. The section cited refers to the international application, and does not apply to US examination of the instant application filed under PCT Rule 371, in the National Stage of the Application. Since Applicant has filed acceptable formal drawings, the argument is now moot.

11. In Paper No. 17, Applicants have presented arguments to the rejections of claims 30, 32-35, 37 and 50-60 under 35 USC 112, first paragraph. However, these rejections have been withdrawn in view of the Declaration under 35 USC 1.132 of John Anthony Charles Archer. The arguments are therefore moot.

New Grounds of Rejection

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Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 53 is drawn to a nucleotide sequence encoding the REG protein of the *ohp* operon of *R. corallina* where it states at lines 2-3, “wherein the nucleotide sequence is at least 90% identical to the one shown in Fig. 4 (SEQ ID NO. 1)”. One species of the genus of nucleotide sequences has been presented in the claims and specification, namely, SEQ ID NO: 1. No additional identifying structural characteristics of the genus of nucleotide sequences encoding the REG protein of the *ohp* operon of *R. corallina* are presented in the specification. The specification does not teach a single representative example of a sequence with 90% identity that encodes a functional REG protein. No information is provided to identify domains or regions of the genus of nucleotide sequences which are necessary to produce a functional REG protein of the *ohp* operon of *R. corallina*. In addition, the prior art is silent as to structural or physical identifying characteristics of the nucleotide sequence encoding a functional REG protein of the *ohp* operon of *R. corallina*. Thus, the instant specification and claims fails to provide the

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necessary structural and physical characteristics of the genus of nucleotide sequences encoding a functional REG protein of the *ohp* operon of *R. corallina*. Therefore, the instant claims and specification lack adequate written description to support the claim to the genus of nucleotide sequences with less than 100% identity to SEQ ID NO. 1 and that encodes a functional REG protein of the *ohp* operon of *R. corallina*.

14. Claim 55 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 55 is drawn to “a modified inducible promoter region which is at least 90% identical to said *ohp* promoter” region of *R. corallina*. One species of the genus of promoter regions has been presented in the claims and specification, namely, it lies in the sequence bounded by base 1035 and base 1450 of SEQ ID NO: 1. No additional identifying structural characteristics of the genus of nucleotide sequences encoding a modified functional promoter region of the *ohp* operon of *R. corallina* are presented in the specification. No information is provided to identify domains or regions of the genus of nucleotide sequences which are necessary to produce a modified functional promoter region of the *ohp* operon of *R. corallina*. The instant specification does not provide a single example of a modified functional promoter region of the *ohp* operon of *R. corallina*. The prior art is silent as to structural or physical identifying characteristics of the nucleotide sequence encoding a modified functional

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promoter region of the *ohp* operon of *R. corallina*. Thus, the instant specification and claims have not provided the necessary structural and physical characteristics of the genus of nucleotide sequences encoding a modified functional promoter region of the *ohp* operon of *R. corallina*. Therefore, the instant claims and specification lack adequate written description to support the claim to the genus of nucleotide sequences with less than 100% identity with SEQ ID NO. 1, and that encodes a modified functional promoter region of the *ohp* operon of *R. corallina*.

15. Claim 61 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 61 is drawn to a “method of introducing an operon protein into a host cell, which operon protein is the regulator (REG) protein the *R. corallina* *ohp* operon or a modification thereof”. One species of the genus of the operon proteins, the regulator (REG) proteins the *R. corallina* *ohp* operon has been presented in the claims and specification, which is the protein of SEQ ID NO: 3. No additional identifying structural characteristics of the genus of the operon modified proteins which are the modified functional regulator (REG) proteins of the *R. corallina* *ohp* operon are presented in the specification. No information is provided to identify domains or regions of the genus of the operon proteins which are modified functional regulator (REG) proteins of the *R. corallina* *ohp* operon which are necessary to produce an operon protein which is modified functional regulator (REG) protein the *R. corallina* *ohp* operon. The prior art

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is silent as to structural or physical identifying characteristics of the operon protein, the regulator (REG) protein the *R. corallina ohp* operon. Thus, the instant specification and claims have not provided the necessary structural and physical characteristics of the genus of the operon proteins which are modified functional regulator (REG) proteins of the *R. corallina ohp* operon. Therefore, the instant claims and specification lack adequate written description to support the claim to the genus of the operon proteins with less than 100% identity with SEQ ID No. 3, and that are modified functional regulator (REG) proteins of the *R. corallina ohp* operon.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 30, 32-35, 37 and 50-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claim 30 recites the limitation "nucleic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. The addition of "molecule" after "nucleic acid" would cure this deficiency.

19. Claim 30 recites the limitation "inducible promoter" in line 3. There is insufficient antecedent basis for this limitation in the claim. The addition of "region" after "inducible promoter" would cure this deficiency.

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20. Claim 32 recites the limitation "nucleic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. The addition of "molecule" after "nucleic acid" would cure this deficiency.

21. Claim 35 provides for the use of a vector, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 35 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Amending claim 35 to read "[a] method of transforming a host cell comprising introducing the vector of claim 32 into a host cell" would cure this defect.

22. Claim 51 recites the limitation "the amino acid sequence shown in Fig. 4" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Changing "the" to "an" would cure this defect.

23. Claim 51 recites "[a] nucleic acid molecule as claimed in claim 50 wherein the nucleotide sequence encodes the amino acid sequence shown in Fig. 4 (SEQ ID NO. 1) from initiator codon 295 to terminator codon 1035." This language is confusing, since it implies that the amino acid

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sequence shown in Fig. 4 is also the sequence shown in SEQ ID NO. 1. This is not the case, since SEQ ID NO. 1 is a nucleotide sequence. In addition, Fig. 4 shows multiple amino acid sequences. Therefore, it is necessary to specifically define which amino acid sequence is being recited in the claim. Further, SEQ ID NO. 1 does not show codons, nor does Fig. 4. Thus the language of claim 51 is vague and indefinite. Amending the claim to state the nucleotide bases which define the ends of the amino acid sequence, and clearly defining the region of the nucleotide sequence being claimed would cure this defect.

24. Claim 51 recites "shown in Fig. 4 (SEQ ID NO. 1) from initiator codon 295 to terminator codon 1035" at lines 3-4. Fig. 4 and SEQ ID NO. 1 do not show codons. Therefore, the metes and bounds of the claim are vague and indefinite. Amending the language to refer to "nucleotide base" instead of "codon" would cure this defect.

25. Claim 53 recites "shown in Fig. 4 (SEQ ID NO. 1) from initiator codon 295 to terminator codon 1035" at lines 3-4. Fig. 4 and SEQ ID NO. 1 do not show codons. Therefore, the metes and bounds of the claim are vague and indefinite. Amending the language to refer to "nucleotide base" instead of "codon" would cure this defect.

26. Claim 54 recites the limitation "nucleic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. The addition of "molecule" after "nucleic acid" would cure this deficiency.

27. Claim 54 recites at lines 3-4 "the nucleotide sequence encoding the *R. corallina ohp* operon described in Fig. 3 (SEQ ID NO. 1). Figure 3 does not show a nucleotide sequence

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encoding the *R. corallina ohp* operon, nor does it show SEQ ID NO. 1. Therefore, the claims are vague and indefinite. Amending the claim to delete the reference to Fig. 3, and to identify the region of the nucleotide sequence shown in SEQ ID NO. 1 would cure this defect.

28. Claim 55 recites "between orfR regulatory gene (terminator codon 1035) and orfT transport (initiator codon 295) shown in Fig. 4 (SEQ ID NO. 1)" at lines 3-4. Fig. 4 and SEQ ID NO. 1 do not show codons. Therefore, the metes and bounds of the claim are vague and indefinite. Amending the language to refer to "nucleotide base" instead of "codon" would cure this defect.

29. Claim 55 recites the limitation "nucleic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. The addition of "molecule" after "nucleic acid" would cure this deficiency.

30. Claim 55 recites the limitation "promoter region" in line 2. There is insufficient antecedent basis for this limitation in the claim. The addition of "inducible" before "promoter region" would cure this deficiency.

31. Claim 56 recites the limitation "nucleic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. The addition of "molecule" after "nucleic acid" would cure this deficiency.

Conclusion

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32. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.

Examiner

April 20, 2003

Remy Yucel
REMY YUCEL, PH.D
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